Amendments to the Drawings:

The attached sheet is a replacement sheet for page 2 of the original set of drawings (original Figures 1b through 1g), in which Figures 1c and 1d have been corrected to show the instrument of the present invention from a top view with apertures on the lateral surface. Care has been taken to avoid the introduction of new matter, and entry is respectfully requested.

REMARKS

The Official Action dated December 20, 2005, has been carefully considered. Accordingly, the changes presented herein, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By present amendment, claim 1 has been amended to recite that the surgical instrument is adapted to separate corneal surface epithelium from the underlying cornea. Support for this amendment may be found in Paragraph 00020 of the specification. New claim 44 has been added to lower the top end of the range disclosed in claim 42. Care has been taken to avoid the introduction of new matter, and entry is respectfully requested.

In the Official Action, the Examiner rejected claims 28, 29, 31-34, and 39-44 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Examiner asserted that it is unclear how the invention is used. Specifically, the Examiner asserted that the specification indicates that apertures 92 are on a lateral surface and that surface 91 is an upper surface, suggesting that apertures 92 may be facing laterally rather than upwardly as shown in Figures 1b, 1c, 1d, and 1g, and that the cannula orientation during the movement from the Figure 1c position to the Figure 1d position suggests that the leading edge is the concave side while the apertures are oriented upwards.

The rejection is traversed. This application has been subject to a restriction requirement, and the method of how the instrument is used is not the subject of the claims of the present application. The claims are directed to a surgical instrument adapted to separate epithelium layers of a cornea, and that instrument is fully and completely disclosed in the specification and in Figures 6-13 (Figures 1a through 1g demonstrate the unelected method claims). The specification at Paragraphs 00020-00023 describes with adequate specificity the various embodiments of the instrument in question, and specifically states: “Apertures 92

are disposed on one lateral surface, relative to contact surface 90 and upper surface 91 of distal section 86 of cannula." See Paragraph 00020. Figures 7, 8, 10, 11, 12 and 13 clearly show the invention with apertures on the lateral surface or side of the instrument, not on the contact surface or the upper surface. Any confusion resulting from Figure 1c and Figure 1d may be the result of a partial perspective view. Attached hereto is a replacement figure sheet with revised Figures 1c and 1d, showing how the instrument in question would appear in a top-down view. Entry of the replacement figure sheet is respectfully requested.

The specification's use of "contact surface" and "upper surface", as well as the general configuration of the instrument, would inform anyone skilled in the art (i.e., an ophthalmologist who would be using the instrument) how to use the instrument. The specification describes the intended use of the instrument as "the separation of the corneal surface epithelium from the underlying cornea." See Paragraph 00020. The instrument is inserted under the epithelium after an incision is made. Id. During separation of the epithelial sheet from the underlying cornea, various media are ejected through the apertures to aid in the separation of the epithelial sheet. Id. It is well known to anyone skilled in the art that the cornea is curved in a lens-like shape. The curvature of the instrument makes its use clear (i.e., the contact surface is in contact with the cornea, and the upper surface is up, opposite the cornea). The apertures are on the lateral surface, as indicated, to eject various media to assist in separation of the epithelial layer from the corner. And Figures 1c and 1d show the media being ejected in the direction of movement of the instrument. The instrument could not be used in the manner suggested by the Examiner (i.e., with the apertures turned up, toward the viewer), as this would cause the curvature of the instrument to not follow the curvature of the cornea, and would result in destructive ripping and tearing of the epithelium. No one skilled in the art would use the instrument in this matter. Thus, the specification and drawings do enable one skilled in the art to make and use the instrument

in question, and the enablement requirement is satisfied. Accordingly, the rejection has been traversed with regard to claims 28, 29, 31-34, and 39-44, and reconsideration is respectfully requested.

The Examiner rejected claims 28, 29, 31-34, and 39-44 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserted that there is no basis in the original disclosure for the limitation in claim 28 that the curvature has a radius substantially equal to a radius of curvature of a cornea of a human eye.

The rejection is traversed. The numerical description of the range of the radius of curvature of the instrument as stated in the specification is substantially equal to the range of radius of curvature of the human cornea, which would be obvious to anyone skilled in the art knowing the described use of the invention. Regardless, claim 28 has been amended to remove that limitation. The rejection has been traversed with regard to claims 28, 29, 31-34, and 39-44, and reconsideration is respectfully requested.

The Examiner rejected claim 41 under 35 U.S.C. 112, second paragraph, as being indefinite. The Examiner asserted that there was no antecedent basis for "said leading side." The rejection is traversed. Claim 41 has been amended to delete the reference to "leading side," and now refers to "side" in accordance with the language of amended claim 28. Reconsideration is respectfully requested.

The Examiner rejected claims 28, 31, 32, 34, 42 and 43 under 35 U.S.C. 102(e) and 35 U.S.C. 103(a) as anticipated by, or as being obvious over, Yaacobi et al. (U.S. Pat. 6,413,245). The Examiner asserts that Yaacobi discloses a connecting end, hollow spatula-like member including an arcuate distal section having a radius of curvature of about 11.5 mm to about 14 mm as recited from col. 64 to col. 6, line 4 (which the Examiner asserts is within the disclosed range of applicant's invention), with one side having a plurality of apertures. The Examiner then asserted that the Yaacobi instrument is inherently capable of

separate epithelium of a cornea, as it could be made a very small size (col. 4, lines 63-66), and that it would have been obvious that the Yaacobi instrument is capable of separating epithelium.

The rejection is traversed. Claim 28 has been amended to recite that the surgical instrument is adapted to separate corneal surface epithelium from the underlying cornea. Applicant finds no suggesting or teaching in Yaacobi of using the instrument of Yaacobi to separate corneal surface epithelium from the underlying cornea. The instrument of Yaacobi is described as a cannula used to deliver drugs into Tenon's capsule of the eye, and the radius of the curvature of the cannula thereby of necessity being substantially equal to the radius of curvature of a human eye. The radius of curvature of the Yaacobi instrument is designed to insure that the instrument does not penetrate the sclera or the periocular tissues (see col. 5, lines 58-63). As the present instrument is designed to be inserted between corneal layers, the radius of curvature of the instrument of the present invention must be compatible with the radius of curvature of the cornea, which is inherently smaller than the radius of curvature of the human eye. While Yaacobi describes the radius of curvature of the drug delivery cannula as being varied, this variation is to match the radius of curvature of the eye of adults with larger or smaller eyes, or pediatric patients with smaller eyes. The radius of curvature of the cornea of such patients would be correspondingly smaller as well. Accordingly, the radius of curvature of the Yaacobi cannula, in order to be used for its described purpose as a sub-Tenon drug delivery device for a patient, must be substantially equal to the radius of curvature of the eye of the patient, and could not have a radius of curvature equal to the cornea.

Contrary to the Examiner's assertions, the Yaacobi instrument is not inherently capable of being adapted to separate corneal surface epithelium from the underlying cornea. First, the disclosed size ranges for the radius of curvature are not coextensive. The size

range of applicant's invention is from about 8 mm to about 12 mm, to cover the variability of cornea sizes from small to large. The size range of the Yaacobi instrument is from 11.5 mm to about 14 mm, to cover the variability of the eyeball from small to large. There is a 0.5 mm overlap of these ranges, but a 11.5 to 12.0 mm Yaacobi instrument would be designed for small eyeballs, and could not be used as a separator for the concomitant small cornea. (It should be noted that the size range of about 10 mm to about 40 mm in original claim 35 was an erroneous range not applicable to the present invention; that size range applied to another instrument disclosed in the specification. See Paragraph 00026 of the specification.) The Yaacobi instrument, as disclosed therein, is not inherently capable of being used to separate corneal surface epithelium from the underlying cornea, and its use for that purpose would result in damage to the epithelium and cornea.

Second, the proposed use of the Yaacobi instrument would change the principle of operation of the Yaacobi instrument, which is impermissible. See MPEP 2143.01(VI) ("The Proposed Modification Cannot Change the Principle of Operation of a Reference"). In fact, any Yaacobi instrument that was modified sufficiently to be used to separate the corneal surface epithelium from the underlying cornea would no longer be able to be used to deliver drugs into the Tenon's capsule of that eye. The proposed or suggested modification cannot render the prior art unsatisfactory for its intended purpose. See MPEP 2143.01(V) (citing In re Gordon, 733 F.2d 900 (Fed. Cir. 1984)).

Accordingly, the rejection of claims 28, 31, 32, 34, 42 and 43 under 35 U.S.C. 102(e) and 35 U.S.C. 103(a) has been traversed, and reconsideration is respectfully requested.

The Examiner rejected claims 33 and 39-41 under 35 U.S.C. 103(a) as being unpatentable over Yaacobi. The Examiner asserted that, while Yaacobi fails to disclose the specific claimed dimensions and number of apertures, it would have been obvious to use the specific claimed dimensions and number of apertures in the Yaacobi instrument.

The rejection is traversed. As discussed above, the underlying rejection of claim 28 has been traversed, and it would not have been obvious to modify Yaacobi to have the specific claimed dimensions and number of apertures as claimed in the present invention where those modifications would have rendered the Yaacobi unable to be used for its intended purpose. See MPEP 2143.01(V). Further, claim 28 as amended is now in allowable form. Thus, claims 33 and 39-41 also are now in allowable form. Accordingly, the rejection with regard to claims 33 and 39-41 is traversed and reconsideration is respectfully requested.

The Examiner rejected claims 29 and 44 under 35 U.S.C. 103(a) as being unpatentable over Yaacobi in further view of Doshi (U.S. Pat. No. 6,443,944). The Examiner asserted that, while Yaacobi did not disclose a trapezoidal cross-section of the spatula-like member, Doshi teaches that the tubular member of a surgical instrument may have a trapezoidal rather than a circular cross-section, and that it would have been obvious to make the cross-sectional shape of the Yaacobi instrument trapezoidal rather than circular.

The rejection is traversed. Claims 29 and 44 are dependent on independent claim 28. As discussed above, claim 28 as amended is now in allowable form. Accordingly, claims 29 and 44 also are now in allowable form.

In addition, the Examiner has failed to establish a *prima facie* case of obviousness. The prior art must contain some suggestion or motivation to modify the reference or to combine the teachings. MPEP 2143.01(I). The burden is on the examiner to explain why the combination of the teachings is proper. MPEP 2142. The mere fact that reference can be combined or modified does not render the resultant combination obvious unless the prior art also suggest the desirability of the combination. MPEP 2143.01(III).

In this regard, both Yaacobi and the present invention disclose a surgical instrument through which fluid is moved and ejected or deposited. The tube of Doshi, in contrast, is

simply used to contain the mechanism by which manipulating arms are controlled inside the body. The tube is not used to separate any body parts or layers. More specifically, Doshi does not suggest or teach anything with regard to the movement of fluid through a surgical instrument, or the shape of a tube through which fluid is moved. There is no motivation or suggestion to combine these references. Accordingly, the rejection with regard to claims 29 and 44 is traversed and reconsideration is respectfully requested.

Accordingly, the rejections of claims 28-29, 31-35 and 39-44 have been traversed, and reconsideration is respectfully requested. It is believed that the above represents a complete response to the rejections under 35 U.S.C. 112, 102(e) and 103(a), and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,

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